

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN**

**Stanley H. Kremen,  
Attorney at Law  
4 Lenape Lane  
East Brunswick, New Jersey 08816  
(732) 593-7294  
Attorney for the Plaintiff**

**TRUTEK CORP.,  
Plaintiff,**

**v.**

**BlueWillow Biologics, Inc.  
ROBIN ROE 1 through 10, gender  
neutral fictitious names, and ABC  
CORPORATION 1 through 10  
(fictitious names).**

**Defendants.**

**CIVIL ACTION No. 2:21-cv-10312-SJM-RSW**

**PLAINTIFF TRUTEK CORP.'S MOTION TO DISMISS DEFENDANT  
BLUEWILLOW BIOLOGIC, INC.'S COUNTERCLAIM COUNTS  
PURSUANT TO FED. R. CIV. P. 12(b)(6)**

Plaintiff Trutek Corp. ("Plaintiff" or "Trutek"), by and through its counsel, Stanley H. Kremen, for its Motion to Dismiss, states as follows:

1. Plaintiff filed its Complaint (Document ECF 1) for this instant lawsuit on February 10, 2021.
2. The Complaint comprised one Count of infringement of Trutek's United States Patent No. 8,163,802 ("the '802 Patent") by Defendant BlueWillow Biologics, Inc. ("Defendant" or "BlueWillow").
3. On May 19, 2021, Defendant timely filed its Answers, Affirmative

Defenses, Counterclaims, and Jury Demand (Document ECF 9).

4. Defendant's Counterclaims comprises two Counts:

Count I: Declaratory Judgment That BlueWillow Does Not Infringe The '802 Patent; and

Count II: Declaratory Judgment of Invalidity of the '802 Patent.

5. For the reasons articulated in Plaintiff's accompanying brief ("Memorandum of Law"), Plaintiff requests that Defendant's Counterclaim Counts I and II be dismissed for failing to state a claim upon which relief can be granted.

**LOCAL RULE CERTIFICATION**

6. On June 4, 2021, I, Stanley H. Kremen, explained the nature of this motion and requested Defendants' concurrence in accordance with Local Rule 7.1. Defendants denied concurrence with Plaintiff's motion.

7. I, Stanley H. Kremen, certify that this document complies with Local Rule 5.1(a) including double-spaced (except for quoted materials, headings, and footnotes), at least one-inch margins on the top, sides, and bottom; consecutive page numbering, and type size of all text and footnotes that is no smaller than 10½ characters per inch (for non-proportional fonts) or 14 point (for proportional fonts). I also certify that it is the appropriate length. Local Rule 7.1(d)(3).

Respectfully submitted,

Dated: June 4, 2021

s/ Stanley H. Kremen  
Stanley H. Kremen  
Attorney for Plaintiff  
Tel: (732) 593-7294  
Fax: (732) 312-5219  
Email: *shk@shk-dplc.com*

**PROOF OF ELECTRONIC SERVICE**

I hereby certify that on June 4, 2021, I presented the foregoing paper, *i.e.*,  
**PLAINTIFF TRUTEK CORP.'S MOTION TO DISMISS DEFENDANT  
BLUEWILLOW BIOLOGIC, INC.'S COUNTERCLAIM COUNTS  
PURSUANT TO FED. R. CIV. P. 12(b)(6)**, to the Clerk of the Court for  
filing and uploading to the ECF system, which will send notification of such  
filing to the attorneys of record listed therein.

s/ Stanley H. Kremen  
Stanley H. Kremen  
Attorney for Plaintiff  
4 Lenape Lane  
East Brunswick, NJ 08816  
Tel: (732) 593-7294  
Fax: (732) 312-5218  
Email: *shk@shk-dplc.com*

1                                   **IN THE UNITED STATES DISTRICT COURT**  
2                                   **EASTERN DISTRICT OF MICHIGAN**

3  
4           **Stanley H. Kremen,**  
5           **Attorney at Law**  
6           **4 Lenape Lane**  
7           **East Brunswick, New Jersey 08816**  
8           **(732) 593-7294**  
9           **Attorney for the Plaintiff**

10                               **TRUTEK CORP.,**  
11                               Plaintiff,

12                               v.

13                               BlueWillow Biologics, Inc.  
14                               ROBIN ROE 1 through 10, gender  
15                               neutral fictitious names, and ABC  
16                               CORPORATION 1 through 10  
17                               (fictitious names).

18                               Defendants.

**CIVIL ACTION No. 2:21-cv-10312-**  
**SJM-RSW**

19                               **MEMORANDUM OF LAW IN SUPPORT OF**  
20                               **PLAINTIFF'S MOTION TO DISMISS DEFENDANT'S**  
21                               **COUNTERCLAIMS**

22  
23  
24           Plaintiff Trutek Corp. submits this memorandum of law in support of  
25 its Motion to Dismiss the Counterclaims submitted by Defendant  
26 BlueWillow Biologics, Inc. under Fed. R. Civ. P. 12(b)(6) for failure to state  
27 a claim upon which relief can be granted.  
28

## TABLE OF CONTENTS

|  | <b>Page</b> |
|--|-------------|
| I. INTRODUCTION  | 1           |
| II. STATEMENT OF MATERIAL FACTS  | 3           |
| III. LEGAL STANDARD  | 4           |
| IV. ARGUMENT   | 4           |
| A. Count I of Defendant's Counter-Complaint Should Be Dismissed Because It Does Not Allege Facts That Support A Facially Plausible Claim.  | 4           |
| B. Count II of Defendant's Counter-Complaint Should Be Dismissed Because It Does Not Allege Facts That Support A Facially Plausible Claim. | 7           |
| V. CONCLUSION  | 9           |

## TABLE OF CASES AND AUTHORITIES

| <b>Cases</b>   | <b>Page</b> |
|--|-------------|
| <i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544, 570 (2007)   | 4, 7, 8, 9  |
| <i>Ashcroft v. Iqbal</i> , 556 U.S. 662, 678 (2009)  | 4, 7, 8, 9  |
| <i>L.M. Sessler Excavating &amp; Wrecking, Inc. v. Bette &amp; Cring, LLC</i> , No. 16-cv-06534-FPG, 2017 U.S. Dist. LEXIS 171708, at *9-10 (W.D.N.Y. Oct. 17, 2017) | 4           |
| <i>Microsoft Corp. v. i4i Limited Partnership</i> , 564 U.S. 91 (2011)   | 8, 9        |
| <b>Statutes</b>  | <b>Page</b> |
| 35 U.S.C. § 101  | 2, 7        |
| 35 U.S.C. § 102  | 2, 7, 8     |
| 35 U.S.C. § 103  | 2, 7, 8     |
| 35 U.S.C. § 112  | 2, 7        |
| 35 U.S.C. § 282  | 8           |

|    |   |             |
|----|---|-------------|
| 1  | <b>Federal Rules of Civil Procedure</b> | <b>Page</b> |
| 2  | Fed. R. Civ. P. 12(b)(6)                | 1, 9        |
| 3  |   |             |
| 4  | <b>Other Authorities</b>                | <b>Page</b> |
| 5  | MPEP § 706                              | 8           |
| 6  |   |             |
| 7  |   |             |
| 8  |   |             |
| 9  |   |             |
| 10 |   |             |
| 11 |   |             |
| 12 |   |             |
| 13 |   |             |
| 14 |   |             |
| 15 |   |             |
| 16 |   |             |
| 17 |   |             |
| 18 |   |             |
| 19 |   |             |
| 20 |   |             |
| 21 |   |             |
| 22 |   |             |
| 23 |   |             |
| 24 |   |             |
| 25 |   |             |
| 26 |   |             |
| 27 |   |             |
| 28 |   |             |

## I. INTRODUCTION

On February 10, 2021, Plaintiff Trutek Corp. ("Plaintiff" or "Trutek") filed a complaint in this lawsuit (Document ECF 1). The Complaint contained one count of infringement of at least Claims 1, 2, and 7 of Trutek's United States Patent No. 8,163,802 ("the '802 Patent"). Trutek is a corporation of the State of New Jersey having its principal office in Somerville, New Jersey.

On May 19, 2021, Defendant BlueWillow Biologics, Inc. ("Defendant" or "BlueWillow") timely filed its Response to Trutek's Complaint. (Document ECF 9.) BlueWillow is a corporation of the State of Delaware, and it has an established place of business in Ann Arbor, Michigan. BlueWillow admits to having developed and sold a product named NanoBio<sup>®</sup> Protect ("NANO BIO Product"). Plaintiff alleges that the NANO BIO Product infringes the claims of the '802 Patent. BlueWillow's Response (Document ECF 9) included Counterclaims consisting of two Counts:

Count I - Declaratory Judgment That BlueWillow Does Not Infringe The '802 Patent; and

Count II - Declaratory Judgment of Invalidity of the '802 Patent.

Count I alleges BlueWillow's entitlement "to a declaratory judgment that it has not infringed and is not infringing the '802 Patent." Count II alleges BlueWillow's entitlement "to a declaratory judgment that the claims of the '802 Patent are invalid."

This Memorandum of Law is in support of Plaintiff's Motion to Dismiss both Counts I and II of Defendant's Counterclaims under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

Defendant's Counterclaims suffer from serious deficiencies. First, in support of Counterclaim Count I, Defendants stated:

1 *BlueWillow has not and does not either literally or under the doctrine*  
2 *of equivalents, directly or indirectly infringe any valid and*  
3 *enforceable claim of the '802 Patent. For example, NanoBio<sup>®</sup> Protect*  
4 *does not restrict the flow of airborne contaminants or particulate*  
5 *matter into nasal passages and/or hold such airborne contaminants or*  
6 *particulate matter outside the body, does not inactivate particulate*  
7 *matter, and does not prevent infection by electrostatically inhibiting*  
8 *harmful particulate matter, as required by the '802 Patent claims.*

9 (Defendant's Response, ECF 9, Pg. 20, ¶ 13.)

10 Defendant's blanket assertion of non-infringement does not address  
11 any element of any allegedly infringed claim of the '802 Patent. Defendant's  
12 example only introduces a scenario not addressed in the claims. No  
13 statement by Defendant in its Answers, Affirmative Defenses, or  
14 Counterclaims support its allegation of non-infringement of at least claims 1,  
15 2, or 7 of the '802 Patent.

16 Second, in Count II, Defendant presents two allegations. First, it  
17 alleges that, "[a]ll claims of the '802 Patent are invalid for failure to comply  
18 with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and  
19 112." Yet, it does not state which claims of the '802 Patent fail to comply  
20 with any of the four statute sections. Specifically, it does not state to which  
21 of the four statute sections the compliance requirement refers. Defendant  
22 does not allege how or why the claims of the '802 Patent fail to comply with  
23 the requirements of any of the four statute sections.

24 Next, Defendant cites four United States Patents and two United  
25 States Patent Application Publications as prior art references that allegedly  
26 invalidate "each claim of the '802 Patent under 35 U.S.C. § 102 and/or §  
27 103." (*Id.* at Pg. 22, ¶ 20.) But, Defendant does not state (1) which of the  
28 two patent statutes are used to invalidate (2) which claims of the '802 Patent  
by (3) which of the six allegedly prior art references. Defendant does not  
allege how and why the claims of the '802 Patent are invalid.



## II. STATEMENT OF MATERIAL FACTS

On April 24, 2012, the '802 Patent issued to Ashok Wahi ("Wahi") who assigned said patent to Trutek. Wahi is the President of Trutek. The '802 Patent is titled, "Electrostatically Charged Multi-Acting Nasal Application Product, and Method." The patented technology was used by Trutek to manufacture NasalGuard<sup>®</sup> products that reduce reactions to airborne allergens and reduce or eliminate reactions to bacterial and virus infections, such as from influenza and the common cold. A user applies the NasalGuard<sup>®</sup> product in and around nasal passages. The product exhibits an electrostatic charge in the nasal passages that restricts and inactivates virus-sized particles.

According to information and belief, sometime in 2020, BlueWillow developed and sold NANOBIO as an over-the-counter pharmaceutical product. Also according to information and belief, NANOBIO products are sold at CVS pharmacies nationwide, and online by Amazon.com. BlueWillow's website advertises that user's apply NANOBIO into the nasal passages.

Sometime in 2020, Wahi suspected that NANOBIO infringes one or more of Trutek's patents. After extensive in-house experimentation on purchased NANOBIO products, indications were that NANOBIO functions by producing an electrostatic charge in and around a user's nasal passages. The Plaintiff surmised that the NANOBIO product infringes at least claims 1, 2, and 7 of the '802 Patent. To validate Trutek's in-house experiments, Trutek submitted samples of NANOBIO products to two outside laboratories for experimental verification. The experiments confirmed that the NANOBIO products exhibit a surface electrostatic charge of the same order of magnitude as Trutek's NasalGuard<sup>®</sup> products.

1        Upon information and belief, just as Trutek's NasalGuard<sup>®</sup> products  
2 work on allergens, contaminants, bacteria, and viruses, the NANO BIO  
3 products work the same way. The NANO BIO products are sold to  
4 customers by Amazon.com. They compete with NasalGuard<sup>®</sup> products that  
5 are also sold on Amazon. Sales of the competing NANO BIO products  
6 deprive Trutek of sales and profits from its own NasalGuard<sup>®</sup> products.

### 7        **III. LEGAL STANDARD**

8        A complaint must allege “enough facts to state a claim to relief that is  
9 plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).  
10 “A claim has facial plausibility when the plaintiff pleads factual content that  
11 allows the court to draw the reasonable inference that the defendant is liable  
12 for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A  
13 plaintiff must allege “specific factual allegations to support each claim”; “a  
14 formulaic recitation of the elements of a cause of action will not suffice.”  
15 *Twombly*, 550 U.S. at 555 (internal quotations omitted). More than  
16 parroting the claim language is required to meet this standard. *L.M. Sessler*  
17 *Excavating & Wrecking, Inc. v. Bette & Cring, LLC*, No. 16-cv-06534-FPG,  
18 2017 U.S. Dist. LEXIS 171708, at \*9-10 (W.D.N.Y. Oct. 17, 2017) (relying  
19 on patent language to describe allegedly infringing conduct does not meet  
20 *Iqbal* and *Twombly* standard).

### 21        **IV. ARGUMENT**

#### 22        **A. Count I of Defendant's Counter-Complaint Should Be Dismissed** 23        **Because It Does Not Allege Facts That Support A Facially** 24        **Plausible Claim.**

25  
26  
27  
28

**Defendant's Count I does not properly state a claim for non-infringement.**

The '802 Patent consists of two independent claims (Claims 1 and 2) and twenty-one dependent claims that depend directly or indirectly from Claim 2. Specifically, Claims 6 and 7 depend from Claim 2.

Independent Claim 1 recites a method for applying a formulation to the skin or tissue of an individual's nasal passages in a thin film, and the method includes:

- a) electrostatically attracting harmful particulate matter to the thin film;
- b) holding the particulate matter in place; and
- c) inactivating the particulate matter by adding at least one ingredient that would render the particulate matter harmless.

Independent Claim 2 recites a formulation that is applied to the skin or tissue of an individual's nasal passages in a thin film, wherein the formulation has at least one cationic agent and at least one biocidic agent, where the formulation:

- a) electrostatically attracts harmful particulate matter to the thin film;
- b) holds the particulate matter in place; and
- c) inactivates the particulate matter and renders it harmless.

Claim 6 depends from Claim 2 and imposes a limitation on Claim 2 such that the at least one cationic agent is benzalkonium chloride.

Claim 7 also depends from Claim 2 and imposes a limitation on Claim 2 such that the at least one biocidic agent is benzalkonium chloride or lysine HCL.

1 Exhibit A (attached hereto) is a photograph of a NANOBIO package  
2 showing that the product is a formulation to be applied to the skin or tissue  
3 of an individual's nasal passages. The packaging claims that the product is a  
4 "nasal antiseptic solution." It also claims to contain benzalkonium chloride.

5 Exhibit 2 of Plaintiff's Complaint (Document ECF 2) is a reproduction  
6 copied from BlueWillow's website. On its website, BlueWillow states,  
7 "NanoBio Protect is composed of positively charged droplets that are 300-  
8 600 nm in size. These droplets are attracted to negatively charged germs on  
9 the skin. The nanodroplets deliver the antiseptic BZK to the surface of the  
10 germs where the germ is inactivated via membrane disruption."

11 BlueWillow claims that the "nanodroplets" adhere to the skin in a thin  
12 film (*i.e.*, 300-600 billionths of a meter). The droplets have a positive  
13 electrostatic charge. Negatively charged germs are attracted to the positively  
14 charged formulation, and they are inactivated and rendered harmless. BZK  
15 is BlueWillow's abbreviation for benzalkonium chloride. Benzalkonium  
16 chloride is a well-known cationic agent that exhibits a positive electrostatic  
17 charge. It is also a well-known biocidal agent that inactivates harmful  
18 bacteria and viruses, which enter the nasal passages as particulate matter.

19 Exhibits 3 and 4 of Plaintiff's Complaint (Documents ECF 3 and ECF  
20 4, respectively) are the reports of laboratory experiments confirming that  
21 NANOBIO exhibits an electrostatic charge of the same magnitude as the  
22 NasalGuard<sup>®</sup> products.

23 Thus, based on the facts stated *supra*, Plaintiff established a *prima*  
24 *facie* case for infringement of Claims 1, 2, 6, and 7 of the '802 Patent.

1  
2 In its Answer, Affirmative Defenses, or Counterclaims (ECF 9),  
3 Defendant does not provide any facts refuting any of the arguments *supra*  
4 showing infringement of Claims 1, 2, 6, or 7 of the '802 Patent. Instead,  
5 Defendant makes a broad unsubstantiated statement that it does not infringe  
6 the claims of the patent. This does not meet the legal standard set forth by  
7 the United States Supreme Court in *Twombly* and *Iqbal*. Defendant's claim  
8 of non-infringement is not facially plausible. Thus, Defendant is not entitled  
9 to a declaratory judgment that BlueWillow does not infringe the '802 Patent.  
10 This Court should dismiss Count I of Defendant's Counterclaims with  
11 prejudice.

12 **B. Count II of Defendant's Counter-Complaint Should Be Dismissed**  
13 **Because It Does Not Allege Facts That Support A Facially**  
14 **Plausible Claim.**

15 **Defendant's Count II does not properly state a claim for patent**  
16 **invalidity.**

17 Defendant's Count II presents two allegations to support its claim for  
18 invalidity of the '802 Patent.

19 First, Defendant alleges that "[a]ll claims of the '802 Patent are invalid  
20 for failure to comply with one or more requirements of 35 U.S.C. §§ 101,  
21 102, 103, and 112." (Document ECF 9, Pg. 21, ¶ 19.) This is a restatement  
22 of Defendant's Third Affirmative Defense (*Id.* at Pg. 17, ¶ 5). However,  
23 Defendant does not state with any specificity which requirements of which  
24 statute sections the Patentee failed to comply. Defendant does not say how  
25 all claims are invalid based on the alleged non-compliance. Defendant's  
26 allegation is a mere formulaic response.

1           Second, Defendant cites four United States Patents and two United  
2 States Patent Application Publications which it claims to be prior art that  
3 invalidates the '802 patent by anticipation under 35 U.S.C. §102 or  
4 obviousness under 35 U.S.C. § 103. (*Id.* at Pg. 22, ¶ 20.) Defendant  
5 precedes the citation of the allegedly prior art references with the phrase,  
6 "for example." Thus, Defendant apparently reserves the right to cite more  
7 allegedly prior art references.

8           But, Defendant does not state which claims are invalid by anticipation  
9 or obviousness over which prior art reference and why they are invalid. To  
10 reject claims of a patent application, Patent Examiners are required to state  
11 such allegations with specificity (United States Patent and Trademark Office  
12 Manual of Patent Examining Procedure, MPEP § 706). Litigants should be  
13 likewise required to do the same.

14           35 U.S.C. § 282(a) provides that, "[a] patent shall be presumed valid.  
15 Each claim of a patent (whether in independent, dependent, or multiple  
16 dependent form) shall be presumed valid independently of the validity of  
17 other claims; dependent or multiple dependent claims shall be presumed  
18 valid even though dependent upon an invalid claim. The burden of  
19 establishing invalidity of a patent or any claim thereof shall rest on the party  
20 asserting such invalidity." On June 9, 2011, the United States Supreme  
21 Court held unanimously (8-0 with Chief Justice recused) that 35 U.S.C. §  
22 282 establishes a presumption of patent validity that an alleged patent  
23 infringer must overcome by clear and convincing evidence in all  
24 circumstances. *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91  
25 (2011). The decision affirmed the "clear and convincing" evidentiary  
26 standard long applied by the Federal Circuit and leaves the law largely  
27 where it has been for more than 50 years.

1 In its Answer, Affirmative Defenses, and Counterclaims, Defendant  
2 does not provide any facts to even barely support its allegations of invalidity,  
3 much less according to a "clear and convincing" evidentiary standard. Once  
4 again, Paragraphs 19 and 20 are mere formulaic recitations lacking any  
5 factual basis. Instead, Defendant makes a broad unsubstantiated statement  
6 that the '802 Patent is invalid. This does not meet the legal standard set forth  
7 by the United States Supreme Court in *Twombly*, *Iqbal*, and *Microsoft*.  
8 Defendant's claim of non-infringement is not facially plausible. Thus,  
9 Defendant is not entitled to a declaratory judgment that the claims of the  
10 '802 Patent are invalid. This Court should dismiss Count II of Defendant's  
11 Counterclaims with prejudice.

## 12 **V. CONCLUSION**

13 In sum, Defendant's Counter-Complaint does not allege facts that  
14 allow one to draw the reasonable inference to support declaratory judgments  
15 against the Plaintiff for non-infringement and/or patent invalidity, or even  
16 what specific allegations of non-infringement and/or patent invalidity that  
17 Plaintiff/Counterclaim Defendant is called on to defend. Such claims for  
18 non-infringement and patent invalidity should be dismissed for failing to  
19 "raise a right to relief beyond the speculative level." Thus Counts I and II  
20 should be dismissed with prejudice under the provisions of Fed. R. Civ. P.  
21 12(b)(6).

# EXHIBIT A



NDC: 74315-001-01

New Patented  
Nanotechnology

**NanoBio<sup>®</sup>Protect**

**Nasal Antiseptic Solution**

Benzalkonium Chloride (0.13%) Antiseptic

**Helps Reduce Risk of Infection**

**Kills 99.99% of Germs**

**Alcohol-Free & Fragrance-Free**

- Comforting when applied
- Moisturizing to the nose & skin
- Persists on skin for 4+ hours



0.61 FL OZ (18 mL) • cotton swabs not included • 40 treatments